



TransMedics Receives FDA Clearance of OCS Lung Solution for Cold Preservation of Lungs

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TransMedics to Provide The Most Comprehensive Lung Preservation Product Portfolio to Lung Transplantation Centers in the U.S.

ANDOVER, Mass., July 29, 2021 /PRNewswire/ -- TransMedics Group, Inc. ("TransMedics") (Nasdaq: TMDX), a medical technology company that is transforming organ transplant therapy for patients with end-stage lung, heart, and liver failure, today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of its OCS™ Lung Solution for use in transplants using cold storage techniques. The solution, which is also cleared as a component of the company's OCS Lung System, is indicated for hypothermic flushing, storage and transportation of donor lungs for transplantation.



"This FDA clearance marks another achievement for TransMedics as we assemble the most comprehensive, market leading portfolio of organ preservation products to meet the clinical needs of the organ transplant market," said Dr. Waleed Hassanein, President and Chief Executive Officer. "With this new clinical indication, we are demonstrating our commitment to establishing TransMedics as the trusted partner to supply world-class organ preservation products to meet customer needs across all transplant indications as we execute on our mission to transform organ transplant therapy for the future."

The OCS Lung System is approved in the U.S. and the Company's OCS Heart System and OCS Liver System are currently under review by the FDA after receiving positive votes by the FDA's relevant advisory panels in April and July respectively.

About the OCS Lung Solution

The OCS Lung Solution is a colorless, sterile, pyrogen-free, colloid-based extracellular low potassium solution for cold flushing, storage and transport of donor lungs for transplantation. The solution is cleared by FDA for use in transplants using TransMedics' OCS Lung System for warm perfusion as well as in transplants using cold storage techniques as a standalone product. It is labeled with a 24-month shelf life.

About the OCS System

The OCS System is the only portable, multi-organ platform for donor lungs, hearts and livers for transplantation. The OCS System mimics the human body by providing donor organs with warm, oxygenated blood perfusion throughout preservation that maintains the organs in a living, functional state. The assessment capabilities of the OCS System enable diagnostic evaluation to allow for the analysis of organ function and viability prior to transplant. Normothermic perfusion on the OCS System optimizes the organ conditions and allows for therapeutic intervention through replenishing oxygen and nutrients.

About TransMedics Group, Inc.

TransMedics is the world's leader in portable extracorporeal warm perfusion and assessment of donor organs for transplantation. Headquartered in Andover, Massachusetts, the company was founded to address the unmet need for more and better organs for transplantation and has developed technologies to preserve organ quality, assess organ viability prior to transplant, and potentially increase the utilization of donor organs for the treatment of end-stage heart, lung, and liver failure.

Forward-Looking Statements

This press release contains forward looking statements with respect to future events. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in or implied by any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Some of the key factors that could cause actual results to differ include: that we continue to incur losses; our need to raise additional funding; our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under our credit agreement to which we will remain subject to until maturity, and our ability to obtain additional financing on favorable terms or at all; the fluctuation of our financial results from quarter to quarter; our ability to use net operating losses and research and development credit carryforwards; our dependence on the success of the OCS; the rate and degree of market acceptance of the OCS; our ability to educate patients, surgeons, transplant centers and private payors of benefits offered by the OCS; the impact of the outbreak of the novel strain of coronavirus and associated containment and remediation efforts; our ability to improve the OCS platform; our dependence on a limited number of customers for a significant portion of our net revenue; the timing of and our ability to obtain and

maintain regulatory approvals or clearances for our OCS products; our ability to adequately respond to FDA follow-up inquiries in a timely manner; the performance of our third-party suppliers and manufacturers; the timing or results of clinical trials for the OCS; our manufacturing, sales, marketing and clinical support capabilities and strategy; attacks against our information technology infrastructure; the economic, political and other risks associated with our foreign operations; our ability to attract and retain key personnel; our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties; our ability to obtain and maintain regulatory approvals or clearance for our OCS products; the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally; and the risks identified under the heading "Risk Factors" and elsewhere in our annual report on Form 10-K for the year ended December 31, 2020, our quarterly reports on Form 10-Q and in any subsequent filings with the Securities and Exchange Commission ("SEC"). Additional information will be made available by our annual and quarterly reports and other filings that we make from time to time with the SEC. These forward-looking statements speak only as of the date of this press release. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law.

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